REMARKS

Claims 78-90 are pending in the subject application. Applicants have herein amended claim 87 to recite several specific anti-CCR5 murine mAbs having one or more CDR regions, which monoclonal antibodies are encoded by the isolated nucleic acid molecule of the invention. The recited mAbs are those, i.e., PA 14, PA 8, PA 9, PA 10, PA 11 and PA12, which were deposited by applicants with the American Type Culture Collection (ATCC). Applicants have also added new claims 91-101 to the application. Support for the amendments to claim 87 and for the new claims may be found, inter alia, in the specification as follows: claims 87, 96, 101: page 13, line 34 to page 14, line 8; page 19 lines 10-13; page 19, line 36 to page 20 line 1; page 22, lines 5-10; page 23, lines 4-5; original claims 65 and 74. Claims 91 and 97: page 17, lines 21-24; Figures 3 and 4. Claims 92 and 98: page 19, lines 2-4; page 23, lines 3-4. Claims 93 and 99: page 19, lines 6, 16, 22; page 23, lines 5-7; original claim 76. Claims 94 and 100: page 19, lines 30-34. This amendment does not involve any issue of new matter. Therefore, entry of this amendment is respectfully requested such that claims 78-101 will be pending.

SEQUENCE:

The Examiner stated that this application contains sequence disclosures that are encompassed by the definition for nucleotide and/or amino acid sequences set forth in 37 C.F.R. §1.821 (a)(1) and (a)(2) and directed applicants' attention to Figure 4. The

Examiner stated that, however, this application fails to comply with the requirements of 37 C.F.R. §1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

In response, applicants submit a paper copy of the Sequence Listing attached hereto as **Exhibit C** in compliance with the requirements of 37 C.F.R. §1.824. In addition, applicants submit herewith a computer readable form (CRF) copy of the "Sequence Listing" as required by 37 C.F.R. §1.825(d). Further, applicants submit herewith as **Exhibit D** a statement in accordance with 37 C.F.R. §1.821 (f), certifying that the substitute computer readable form containing the nucleic acid and/or amino acid sequences as required by 37 C.F.R. §1.821(e) contains the same information which was submitted as the "Sequence Listing" and contains no new matter.

Restriction under 35 U.S.C. §121

The Examiner requires restriction to one of the following inventions under 35 U.S.C. §121:

I. Claim 78, drawn to a murine anti-CCR5 antibody, classified in Class 530, subclass 388.22.

II. Claims 79-80, drawn to a humanized anti-CCR5 antibody, classified in Class 530, subclass 388.15.

III. Claims 81-82, drawn to nucleic acids encoding a light chain of an anti-CCR5 monoclonal antibody, classified in Class 536, subclass 23.53.

IV. Claims 83-84, drawn to nucleic acids encoding a heavy chain of an anti-CCR5 monoclonal antibody, classified in Class 536, subclass 23.53.

V. Claims 85-86, drawn to nucleic acids encoding a Fab portion of an anti-CCR5 monoclonal antibody, classified in Class 536, subclass 23.53.

VI. Claims 87-88, drawn to nucleic acids encoding CDR regions of an anti-CCR5 monoclonal antibody, classified in Class 536, subclass 23.53.

VII. Claims 89-90, drawn to nucleic acids encoding the variable domain of an anti-CCR5 monoclonal antibody, classified in Class 536, subclass 23.53.

The Examiner stated that the inventions are distinct, each from the other because of the following reasons. The Examiner stated that the products of Groups I-VII differ from one another in their physical properties and molecular weight and are novel and unobvious in view of each other. The Examiner stated that Groups I and II are directed to structurally distinct antibodies. The Examiner stated that Groups III-VII are directed to different

nucleic acid sequences encoding structurally distinct proteins. The Examiner stated that, therefore, the inventions of Groups I-VII are patentably distinct. The Examiner further stated that because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications and divergent subject matter, and because the searches for the individual groups are not coexistensive, restriction for examination purposes as indicated above is proper.

The Examiner also stated that claims 81-90 read on both the murine monoclonal antibody of claim 78 and the humanized antibodies of claims 79-80. The Examiner stated that, should applicants elect any of the inventions of Group III-VII, applicants are required to further elect either nucleic acids reading on the murine monoclonal antibody as set forth in claim 78, or nucleic acids reading on the humanized antibody as set forth in claims 79-80. The Examiner stated that these nucleic acids encode different peptides and themselves differ in their primary nucleic acid sequence and are novel and unobvious in view of each other and are, therefore, patentably distinct.

In response to this restriction requirement, applicants' undersigned attorney, on behalf of applicants, hereby elects, with traverse, to prosecute the claims of Examiner's Group VI, nos. 87-88, drawn to nucleic acids encoding CDR regions of an anti-CCR5 monoclonal antibody. Furthermore, in accordance with the additional requirement set forth on p.4 of the Office Action, i.e., to further

elect either nucleic acids reading on the murine monoclonal antibody (as set forth in claim 78), or nucleic acids reading on humanized antibodies ( as set forth in claims 79-80), applicants hereby elect nucleic acids reading on murine monoclonal antibodies. Claim 87 has therefore been amended to recite several specific anti-CCR5 murine monoclonal antibodies having one or more CDR regions encoded by the claimed isolated nucleic acid molecule.

Applicants have additionally added new claims 91-95 and 98-101 which depend, directly or indirectly, from claim 87 of Examiner's Group VI, as elected, and which should thus be examined together with the claims of Group VI.New independent claim 96, and new claim 97 which depends therefrom, are also submitted herewith. Claim 96 recites an embodiment wherein the nucleic acid molecule of the invention encodes an anti-CCR5 murine monoclonal antibody, or portion therefore, wherein the portion comprises one or more CDR regions. The anti-CCR5 monoclonal antibody of the claim is selected from the same murine antibodies as recited in claim 87, i.e., PA 14, PA 8, PA 9, PA 10, PA 11 and PA 12. The invention recited in claims 96-97 is thus clearly not "distinct" from those recited in claims 87-88 and 91-101 as that term is used in 35 U.S.C. §121. Therefore claims 96 and 97 should be examined together with claims 87-88, 91-95 and 98-101.

Applicants note that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be

restricted to one of the inventions." [Emphasis added]. Applicants request that the restriction of Examiner's Group V and Examiner's Group VII from Examiner's Group VI (elected herein with traverse) be withdrawn in view of the fact that the claims of Examiner's Groups V and VII are not independent of the Examiner's Group VI. Applicants maintain that the claims of Examiner's Group VI and Examiner's Groups V and VII do not define inventions which are patentably distinct from one another.

Under M.P.E.P. §802.1 "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation and effect." Turning first to the claims of Examiner's Group V, claim 85 of that Group recites an embodiment of the invention directed to one or more isolated nucleic acid molecules encoding the Fab portion of the monoclonal antibody of any one of claims 78-80. Claim 78 is specifically directed to the PA 14 anti-CCR5 antibody (ATCC Accession No. HB-12610), as well as to any other antibodies which bind to the same epitope as PA 14. Thus claim 85 is directed to a specific portion, i.e., the Fab portion, of the antibodies included within claim 78. Moreover, it is well understood by one of ordinary skill in this art that the Fab portion of an antibody includes the variable region of the antibody. Moreover, it is these variable regions which contain the complementarity determining regions, i.e., the "CDRs". Thus, claim 85 (and claim 86 which depends from claim 85) is specifically directed to a CDR-containing region of one of the specific anti-CCR5 murine monoclonal antibodies, i.e., PA 14, recited in claim 87 as now amended. Since the claims of Examiner's Group VI and Examiner's Group V thus are all directed to at least

one specific anti-CCR5 murine monoclonal antibody having one or more CDR region that recognizes and binds to the CCR-5 epitope, the antibodies included in both groups of claims are all structurally and functionally equivalent. As such, the claims of Examiner's Group V should be examined together with those of Examiner's Group VI.

Turning next to the claims of Examiner's Group VII, which also should be examined together with those of Group VI, claim 89 of the Examiner's Group VII is directed to one or more nucleic acid molecules encoding the variable domain of the monoclonal antibody of any one of claims 78-80. As noted above in the discussion of the Examiner's Group V claims, the variable domains of the subject anti-CCR5 murine monoclonal antibodies recited, e.g., in claim 78 (i.e., the PA 14 antibody or other antibody which binds to the same epitope as PA 14) in fact contain the CDR regions of such antibody(s). As it is the function of the isolated nucleic acid molecule(s) of the present invention to encode these CDR regions, applicants submit that the nucleic acid molecules recited in claim 89 of Group VII (and claim 90 which depends from claim 89) are structurally and functionally equivalent to the nucleic acid molecule(s) which are the subject of claims 87-88 of elected Group VI. For this reason, the claims of Examiner's Group VII should be examined together with the claims of Examiner's Group VI.

Applicants therefore respectfully assert that the Examiner's Groups V, VI and VII do not claim inventions which are independent from each other because the groups are not distinct under MPEP §806.05. Therefore, restriction among these three groups is improper under

35 U.S.C. §121.

Additionally, applicants point out that under M.P.E.P. §803, the Examiner must examine (at least) Groups V, VI and VII of the application on the merits, even if they include claims to distinct inventions, if the search and examination of these groups can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants maintain that there would <u>not</u> be a serious burden on the Examiner if restriction were not required among Examiner's Groups V, VI, and VII. A search of prior art with regard to these Groups will reveal whether any prior art exists with regard to nucleic acid molecule(s) that encode at least one CDR region on a murine monoclonal antibody that specifically recognizes the CCR5 epitope. Therefore, since such an examination would not present any serious burden to the Examiner, applicants respectfully submit that the Examiner must examine the claims of Groups V, VI, and VII on their merits.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement among at least Groups V, VI and VII and examine the claims of at least those Groups on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned

attorney invites the Examiner to telephone at the number provided below.

No fee, other than the enclosed $1079.00 fee, which includes the $980.00 fee for a five month extension and the $99.00 fee for additional claims 91-101 is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Mark A. Farley 3/25/02

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